

NOTE TO: Obstetrics & Gynecology Devices Panel 5879 '99 SEP 27 110 58
FROM: Elisa Harvey, DVM, PhD
Executive Secretary, Obstetrics and Gynecology Devices Panel
Center for Devices & Radiological Health/FDA
DATE: September 3, 1999
SUBJECT: Background Materials for 10/4/99 Panel Meeting

Enclosed are the materials we would like you to review for the October 4, 1999 panel meeting. These materials are not confidential, since there is no proprietary information included.

As indicated, the morning session will be devoted to a discussion of study requirements for vaginal barrier contraceptives. The afternoon session will be devoted to a discussion of study requirements for devices used in non-extirpative methods of treating uterine fibroids.

Both sessions will include introductions by Colin Pollard, Chief of the Obstetrics and Gynecology Devices Branch, and Dr. Diane Mitchell, Obstetrician/Gynecologist and Medical Officer for the Obstetrics and Gynecology Devices Branch. We intend to also have the following guest speakers to provide additional expertise as well:

Morning: James Trussell, Ph.D.
Office of Population Research
Princeton University

Dr. Trussell will be presenting his recent publication on contraceptive failure (included in this package).

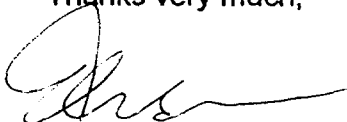
Afternoon: Robert Vogelsang, M.D.
Northwest Memorial Hospital
Department of Radiology

Dr. Vogelsang is an interventional radiologist who will be discussing uterine artery embolization.

The panel meeting will begin with a required 1 hour closed session in which FDA presents confidential information to the panel about ongoing review activities, followed by the morning and afternoon sessions (with breaks and lunch!).

If you have any questions about this meeting, please don't hesitate to contact me for assistance at 301-594-1180 x 141. We look forward to your participation.

Thanks very much,



Elisa Harvey

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